

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:) Examiner: Angela Marie Hoffa
Thomas KOEHLER et al.)
Serial No.: 10/598,004) Art Unit: 3768
Filed: May 10, 2007) Confirmation No.: 8994
February 15, 2005)
as PCT/IB2005/050576)
For: **DRUG APPLICATION**)
DURING A CT SCAN)
Attorney Docket: DE040056US1) Cleveland, Ohio 44143

REPLY BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir / Madam:

This Reply Brief is being filed in response to the Examiner's Answer dated March 3, 2011 in the appeal of the patent application identified above.

CERTIFICATE OF ELECTRONIC TRANSMISSION

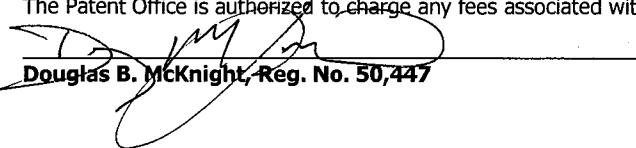
I certify that this **REPLY BRIEF** in connection with U.S. Serial No. 10/598,004 is being filed on the date indicated below by electronic transmission with the United States Patent and Trademark Office via the electronic filing system (EFS-Web).

May 3 2011
Date

Patricia A Heim
Patricia A. Heim

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Douglas B. McKnight, Reg. No. 50,447

ARGUMENT IN RESPONSE TO EXAMINER'S ANSWER

As more fully discussed in the initial Appeal Brief and in the Examiner's Answer, the following two grounds of rejection are to be reviewed on appeal:

- (A) The rejection of claims 1-4, 7, 8-9, 10, 12-14 and 17-19 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,397,098 to Uber; and
- (B) The rejection of claims 5-6, 15-16 and 20 under 35 U.S.C. § 103 as being unpatentable over Uber alone.

The applicant hereby submits the following arguments in response to the Examiner's Answer. While the Examiner's Answer relies upon the same two grounds of rejection, much of the reasoning contained in the Examiner's Answer was presented for the first time therein. (As noted in the Appeal Brief at page 6, the August 2, 2010 Final Office Action completely ignores the limitation in the independent claims reciting a controlled change of the heart beat rate of the patient "to reduce variations in the heart beat rate during" an imaging scan.) The applicant respectfully requests that the prior art rejections of all pending claims 1-10 and 11-20 be reversed.

A. Claims 1-4, 7, 8-9, 10, 12-14 and 17-19 Are Not Anticipated by Uber

Claims 1-4, 7, 8-9, 10, 12-14 and 17-19 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,397,098 to Uber ("Uber"). Those rejections are improper, for the reasons set forth in the Appeal Brief as supplemented by this Reply Brief.

The Examiner's Answer continues to maintain independent claims 1, 8, 10 and 18 are anticipated by Uber in part because Uber discloses the claim limitation reciting a controlled change of the heart beat rate of the patient "to reduce variations in the heart beat rate during" an imaging scan. Uber, however, fails to disclose that limitation for the following reasons. Therefore, the claim rejections on the basis of anticipation by Uber should be reversed.

The essence of the Examiner's reasoning is set forth at pages 6-8 of the Examiner's Answer, under the "Response to Argument" section heading. That reasoning, however, relies on portions of the Uber disclosure which the Examiner reads out of context. The disclosure in Uber

relied upon by the Examiner is underlined below, set forth in the proper context of the overall Uber disclosure:

Uber, Column 10, Lines 12-65

Other sensors or sensing equipment can be in communicative connection with interface 90. For example, a sensor or sensors (not shown) can be part of system 10 to provide direct measurements of the concentration of the fluid medium and/or the contrast enhancement agents within the patient's body. Another example is bar code readers which input information about the contrast media including but not limited to volume, concentration, manufacture date, manufacturer. Moreover, interface 90 can be in unidirectional or bi-directional communicative connection with a sensing and/or measuring device 130 that provides data on one or more physiological conditions of the patient. For example, device 130 can be a heart rate or blood pressure monitor.

Previous injector systems have contained an electrocardiograph (ECG) that is used to set start of injection trigger points synchronized with various portions of the cardiac cycle. In the present invention, other equipment such as heart rate or blood pressure monitors may be used to provide patient physiological data to control the injection or imaging process, especially during an injection. For example, during ultrasound cardiac stress echo imaging, vasodilator and vasoconstrictor drugs are administered to increase and decrease cardiac output load. Connected sensors for monitoring heart rate and blood pressure may be used to initiate, terminate or adjust the injection process when these parameters reach certain levels. The output from these sensors can also be used to adjust other aspects of the imaging process, such as scanner settings. Unlike prior systems, the present invention allows isolation, digital communication, bi-directional or two-way communication and/or communication with an imaging system.

In addition, it may be useful to control the delivery of some therapeutic or diagnostic agents during contrast imaging based on display or signal information from the imager as a result of the imaging procedure. For example, during ultrasound cardiac stress echo procedures, a drug, Dobutamine, which is a cardiotonic or cardiovascular stressor agent, is often used to increase cardiac stress so that cardiac parameters can be measured and quantified. (Dobutamine is a synthetic derivative of dopamine, characterized by prominent inotropic but weak chronotropic and arrhythmogenic properties.) An injection system may be used to control the delivery of the stressor drug during an enhanced procedure based on visual information from the imager, such as peak flow rate in a vessel from a Doppler image, the intensity of a perfused tissue region, vessel geometry measurements, or heart chamber geometry measurements during various portions of the cardiac cycle. The delivery of such a drug

can also be controlled by the signal at the imager before it is generated into a display, for example, using acoustic intensitometry. This concept can be extended to other imaging modalities and to the administration of other therapeutic or diagnostic drugs or substances.

Uber, Column 13, Line 66 to Col. 14, Line 21

Closed loop control can be used to control the concentration of the enhancement agent in a region of tissue. The level of enhancement required, the level of enhancement or the time response of enhancement increase or decay can be used to observe tissue perfusion, since the enhancement agent will be present in the small vessels that perfuse the region of interest. This technique can also be combined with the use of vasoconstrictor/vasodilator drugs, physical stress, or other means to induce cardiovascular stress to make changes in perfusion more pronounced or detectable.

Another diagnostic application for interface 90 is to control parameters such as concentration, flow rate or time or timing of injection based on data of a physiologic parameter, such as heart rate, provided by external device 130. An example of a procedure is closed loop drug delivery of cardiac stress agents while imaging. In this technique, a stressor agent is injected and controlled based on heart rate. Once a target heart rate is achieved it may be useful to synchronize and control the level of injected enhancement agent, or to provide bolus injection control for diagnostic purposes. In that regard, information from imaging unit 100 can be used to control the delivery of the enhancement agent. . . .

See Uber, at col. 10, lines 12-65 and at col. 13, line 66 to col. 14, line 21 (emphasis added); Examiner's Answer, at pages 4 and 6-7. The Examiner concludes, from the underlined disclosure, that "Uber discloses the administration of a drug to the patient, during the CT scan, to control the heart beat rate of the patient during a stress test." See Examiner's Answer, at page 6 (emphasis added). The Examiner's conclusion is not, in fact, supported by the disclosure in Uber when read in the complete context set forth above, for at least two reasons.

First, Uber does not disclose control of the heart beat rate "during a stress test." Rather, as can be seen from the disclosure of Uber when read as a whole, all that it teaches is monitoring the patient's heart beat rate (or other physiological data) to control the injection or imaging process. That is, when the heart beat rate reaches a target level the contrast agent injection process is initiated, terminated or adjusted, or scanner settings are adjusted. See Uber, col. 10, lines 25-65 and col. 10, line 66 to col. 11, line 21. Uber discloses applying vasodilator and vasoconstrictor drugs while monitoring a patient's heart beat rate during an imaging scan to achieve a target heart

beat rate. Once the target heart beat rate is achieved then one or more of the imaging system or contrast agent injection parameters is initiated, terminated or adjusted. Uber entirely fails to disclose continued monitoring of the heart beat rate after the target heart beat rate is achieved, as part of some sort of “stress test” or otherwise. So far as the disclosure in Uber is concerned, reaching the target rate triggers a change in contrast agent injection or scanner settings — but that is all Uber discloses.

Second, even if the actual process as described in the quotations from Uber set forth above is considered a “stress test”, still even then such a “stress test” is dramatically different from the detailed description provided by the Examiner’s Answer at pages 6-8. There is no disclosure in Uber of a process as described by the Examiner, regardless of whether it is called a “stress test.” This can be seen from the context of the quotations from Uber provided above. The actual disclosure of Uber does not bear the weight placed upon it by the Examiner’s analysis. Uber never discloses attempting to reach a target heart beat rate and, once achieved, reducing variations in the heart beat rate.

For the foregoing reasons, all the anticipation rejections based on Uber should be reversed and the claims allowed because Uber fails to disclose a controlled change of the heart beat rate of the patient “to reduce variations in the heart beat rate during” an imaging scan.

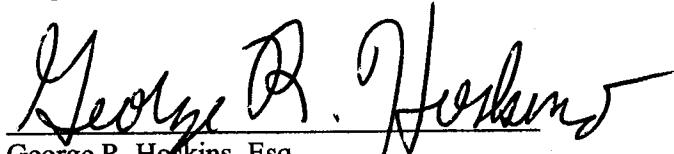
B. Claims 5-6, 15-16 and 20 are Not Unpatentable As Obvious Over Uber Alone.

Claims 5-6, 15-16 and 20 stand rejected under 35 U.S.C. § 103 as being obvious over Uber alone. Those rejections are improper, for the reasons already set forth in the Appeal Brief. No additional comments are provided here.

C. Conclusion

All the pending claims are patentable over the art of record cited in the Final Office Action and discussed in the Examiner's Answer. The rejections of these claims should therefore be reversed, and the claims allowed.

Respectfully submitted,



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